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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,700	07/06/2001	Keith D. Allen	R-616	3949

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EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,700	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3/4/03 .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7,9,11-16 and 23-29 is/are pending in the application.

4a) Of the above claim(s) 1-7,9,11-16 and 23 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's amendment filed on 3/4/03 has been entered. Claims 8, 10, and 17-22 have been cancelled. New claims 24-29 have been added. Claims 1-7, 9, 11-16, and 23-29 are pending. Claims 24-29 are under current examination.

Election/Restrictions

Claims 1-7, 9, 11-16, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The amendment to the specification, which describes Figure 2A, has been entered.

Drawings

Substitute Figure 2A has been accepted by the Examiner. All the drawings have been accepted by the Examiner.

Sequence Compliance

In view of the corrections to Figure 2A, submitted on 3/4/03, the instant application is now in sequence compliance.

Information Disclosure Statement

Applicant's explanation regarding the IDS in question is acknowledged by the Examiner.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejections under the first paragraph of 35 U.S.C. 112 have been withdrawn.

The following new grounds of rejection under 35 USC § 112, 2nd paragraph, have been necessitated by the addition of new claims 28-29:

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is directed to a method of producing a transgenic mouse, wherein method step (b) recites introducing a CRFR2 gene targeting construct into a murine embryonic stem cell. However, the term murine encompasses both mice and rats. The claim is indefinite because it is unclear how a transgenic mouse can be produced when using a rat embryonic stem cell. It appears that Applicants have inadvertently used improper terminology to describe a mouse embryonic stem cell. Appropriate correction is required. Amending the claim to read on a mouse embryonic stem cell will obviate this rejection. Claim 29 depends from claim 28.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Coste et al (Nature Genetics, 2000, 24: 403-409).

The claims are directed to a transgenic non-human animal comprising a disruption in a CRFR2 gene and a method for producing a transgenic mouse comprising a disruption in a CRFR2 gene.

For the purposes of the this rejection a CRFR2 gene is interpreted to be a CRHR2. This interpretation has been made because the prior art as set forth in the specification on pages 1-4 sets forth that a CRFR2 gene and a CRHR2 gene are the same. The difference being in name only, corticotropin-releasing factor receptor as opposed to corticotropin-releasing hormone receptor.

Coste et al teach a transgenic mouse comprising a homozygous disruption in the CRHR2 gene, wherein the disruption results in no production of CRHR2. The mouse of Coste et al exhibits phenotypes which differ from the claimed mouse. However, the since the mouse of Coste et al meets the instant claim limitations of a genome comprising a homozygous disruption of CRFR2 (CRHR2), any phenotypes associated with disruption of the CRFR2 gene are inherent properties of the mouse, since it does not appear that the mice are structurally different. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence

showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. Coste et al teach that the transgenic mouse is created by introducing a targeting vector into ES cells, transferring the ES cells to a blastocyst and then implanting the blastocyst into a pseudopregnant female mouse, wherein said female mouse gives birth to a chimeric mouse, and breeding said chimeric mouse to produce the transgenic mouse. See page 403, column 1, first paragraph as well as the Materials and Methods section on pages 406-408.

Thus, the teachings of Coste et al anticipate all of the instant claim limitations.

Applicant's arguments filed 3/4/03 have been fully considered but they are not persuasive. Applicants have argued that Coste et al does not anticipate the claimed mouse because Coste et al does not teach a mouse having the same phenotypes as recited in the claims. See pages 6-7 of the amendment.

In response, the Examiner asserts the claimed mouse and the mouse of Coste appear to be the same structurally; both comprise genomes that comprise homozygous disruptions of the endogenous CRFR2 gene. The Examiner further asserts that any phenotype associated with disruption of CRFR2 must be inherent to the mouse of Coste et al. A product and its properties cannot be separated and the recognition of new properties does make and old product allowable. As such, Coste anticipates all of the limitations of new claims 24-29.

Claims 24-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Bale et al (Nature Genetics, 2000, 24: 410-414).

The claims are directed to a transgenic non-human animal comprising a disruption in a CRFR2 gene and a method for producing a transgenic mouse comprising a disruption in a CRFR2 gene.

For the purposes of the this rejection a CRFR2 gene is interpreted to be a CRHR2. This interpretation has been made because the prior art as set forth in the specification on pages 1-4 sets forth that a CRFR2 gene and a CRHR2 gene are the same. The difference being in name only, corticotropin-releasing factor receptor as opposed to corticotropin-releasing hormone receptor.

Bale et al teach a transgenic mouse comprising a homozygous disruption in the CRHR2 gene, wherein the disruption results in no production of CRHR2. The mouse of Bale et al exhibits phenotypes which differ from the claimed mouse. However, the since the mouse of Bale et al meets the instant claim limitations of a genome comprising a homozygous disruption of CRFR2 (CRHR2), any phenotypes associated with disruption of the CRFR2 gene are inherent properties of the mouse, since it does not appear that the mice are structurally different. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing

that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. Bale et al teach that the transgenic mouse is created by introducing a targeting vector into ES cells, transferring the ES cells to a blastocyst and then implanting the blastocyst into a pseudopregnant female mouse, wherein said female mouse gives birth to a chimeric mouse, and breeding said chimeric mouse to produce the transgenic mouse. See page 410, column 1, first paragraph bridging to page 411 as well as the Materials and Methods section on page 412.

Thus, the teachings of Bale et al anticipate all of the instant claim limitations.

Applicant's arguments filed 3/4/03 have been fully considered but they are not persuasive. Applicants have argued that Bale et al does not anticipate the claimed mouse because Bale et al does not teach a mouse having the same phenotypes as recited in the claims. See page 7 of the amendment.

In response, the Examiner asserts the claimed mouse and the mouse of Bale appear to be the same structurally; both comprise genomes that comprise homozygous disruptions of the endogenous CRFR2 gene. The Examiner further asserts that any phenotype associated with disruption of CRFR2 must be inherent to the mouse of Bale et al. A product and its properties cannot be separated and the recognition of new

properties does make and old product allowable. As such, Bale anticipates all of the limitations of new claims 24-29.

Claims 24-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Kishimoto et al (Nature Genetics, 2000, 24: 415-419).

The claims are directed to a transgenic non-human animal comprising a disruption in a CRFR2 gene and a method for producing a transgenic mouse comprising a disruption in a CRFR2 gene.

For the purposes of the this rejection a CRFR2 gene is interpreted to be a CRHR2. This interpretation has been made because the prior art as set forth in the specification on pages 1-4 sets forth that a CRFR2 gene and a CRHR2 gene are the same. The difference being in name only, corticotropin-releasing factor receptor as opposed to corticotropin-releasing hormone receptor.

Kishimoto et al teach a transgenic mouse comprising a homozygous disruption in the CRHR2 gene, wherein the disruption results in no production of CRHR2. The mouse of Kishimoto et al exhibits phenotypes which differ from the claimed mouse. However, the since the mouse of Kishimoto et al meets the instant claim limitations of a genome comprising a homozygous disruption of CRFR2 (CRHR2), any phenotypes associated with disruption of the CRFR2 gene are inherent properties of the mouse, since it does not appear that the mice are structurally different. Where the claimed and prior art products are identical or substantially identical in structure or composition, or

are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. Kishimoto et al teach that the transgenic mouse is created by introducing a targeting vector into ES cells, transferring the ES cells to a blastocyst and then implanting the blastocyst into a pseudopregnant female mouse, wherein said female mouse gives birth to a chimeric mouse, and breeding said chimeric mouse to produce the transgenic mouse. See page 415, column 1, first paragraph, Figure 1 on page 415 as well as the Materials and Methods section on pages 418.

Thus, the teachings of Kishimoto et al anticipate all of the instant claim limitations.

Applicant's arguments filed 3/4/03 have been fully considered but they are not persuasive. Applicants have argued that Kishimoto et al does not anticipate the claimed mouse because Kishimoto et al does not teach a mouse having the same phenotypes as recited in the claims. See page 7 of the amendment.

In response, the Examiner asserts the claimed mouse and the mouse of Kishimoto appear to be the same structurally; both comprise genomes that comprise homozygous disruptions of the endogenous CRFR2 gene. The Examiner further asserts that any phenotype associated with disruption of CRFR2 must be inherent to the mouse of Kishimoto et al. A product and its properties cannot be separated and the recognition of new properties does make and old product allowable. As such, Kishimoto anticipates all of the limitations of new claims 24-29.

Claims 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (US 6,353,152; effective filing date of 7/15/1999).

The claims are directed to a transgenic non-human animal comprising a disruption in a CRFR2 gene and a method for producing a transgenic mouse comprising a disruption in a CRFR2 gene.

Lee et al teach a transgenic mouse comprising a homozygous disruption in the CRHR2 gene, wherein the disruption results in no production of CRHR2. The mouse of Lee et al exhibits phenotypes which differ from the claimed mouse. However, the since the mouse of Lee et al meets the instant claim limitations of a genome comprising a homozygous disruption of CRFR2 (CRHR2), any phenotypes associated with disruption of the CRFR2 gene are inherent properties of the mouse, since it does not appear that the mice are structurally different. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or

obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. Lee et al teach that the transgenic mouse is created by introducing a targeting vector into ES cells, transferring the ES cells to a blastocyst and then implanting the blastocyst into a pseudopregnant female mouse, wherein said female mouse gives birth to a chimeric mouse, and breeding said chimeric mouse to produce the transgenic mouse. See column 8 and throughout entire document.

Thus, the teachings of Lee et al anticipate all of the instant claim limitations.

Applicant's arguments filed 3/4/03 have been fully considered but they are not persuasive. Applicants have argued that Lee et al does not anticipate the claimed mouse because Lee et al does not teach a mouse having the same phenotypes as recited in the claims. See page 7 of the amendment.

In response, the Examiner asserts the claimed mouse and the mouse of Lee appear to be the same structurally; both comprise genomes that comprise homozygous disruptions of the endogenous CRFR2 gene. The Examiner further asserts that any phenotype associated with disruption of CRFR2 must be inherent to the mouse of Lee

et al. A product and its properties cannot be separated and the recognition of new properties does make and old product allowable. As such, Lee anticipates all of the limitations of new claims 24-29.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER